REMARKS

The Office Action mailed January 26, 2006 has been carefully considered. Applicants wish to thank the Examiner for the effort in evaluating this application. The following is noted:

Claims 10-15, and 18 remain pending in this application. It is believed that the claims as presently amended have overcome the examiner's rejections as detailed in the following remarks.

Claim Rejections – 35 USC §112

Claims 10-11, 14-15 and 18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 10 and 18 recite the term "lipid metabolism disorder". This term is believed to be known to those skilled in the art, and it is used in the specification on page 13 at lines 30-32 as referring especially to "hyperlipidemia or metabolic syndrome". As evidence that the term is known to those skilled in the art, the Examiner is referred to the web site of a thesaurus at the U.S. National Institutes of Health at:

http://crisp.cit.nih.gov/Thesaurus/00012880.htm

The definition provided there is: "condition in which there is a deviation or interruption in the processing of lipids in the body: synthesis, absorption, transport, storage, and utilization".

Claim 10 also recites the term "metabolic syndrome". This term is also believed to be known to those skilled in the art. As evidence that it is so known, the Examiner is referred to the web site of the same thesaurus at:

http://crisp.cit.nih.gov/Thesaurus/00004673.htm

The definition provided there is: "a multifaceted syndrome characterized by clustering of insulin resistance and hyperinsulinemia, associated with dyslipidemia, essential hypertension, abdominal obesity, glucose intolerance or noninsulin dependent diabetes mellitus, and an increased risk of cardiovascular events".

Accordingly, since the terms cited in the present Office Action are known to a skilled person, who would be aware of the terminology recognized by the NIH, it has not been shown

by the Office that the cited terms are indefinite. Withdrawal of the rejections under 35 U.S.C. §112 of claims 10, 18 and the claims that depend from the rejected base claims is therefore respectfully requested.

Claim Rejections – 35 USC §103

Claims 10-15 and 18 stand rejected under 35 U.S.C. 103(a) as being obvious over Frick and Castaner. It is asserted in the present Office Action that "one of ordinary skill in the art would have reasonably expected that combining the composition of Frick et al and the composition of Castaner et al both known to be useful for the same purpose, would improve the therapeutic effects for treating the same diseases, and/or would produce additive therapeutic effects in treating the same." The present Office Action asserts that under the Graham test the presently claimed invention is obvious.

However, as stated in MPEP 2141 (I), quoting the CAFC in Stratoflex v. Aeroquip, 713 F.2d 1530, 1540, 218 USPQ 871, 880 (Fed. Cir. 1983):

> A requirement for "synergism" or a "synergistic effect" is nowhere found in the statute, 35 U.S.C. When present, for example in a chemical case, **synergism may point toward nonobviousness [emphasis added],** but its absence has no place in evaluating the evidence on obviousness. The more objective findings suggested in *Graham*, supra, are drawn from the language of the statute and are fully adequate guides for evaluating the evidence relating to compliance with 35
> U.S.C. § 103. *Bowser Inc. v. United States*, 388 F. 2d 346, 156 USPQ 406 (Ct. Cl. 1967).

The synergistic effects shown in the specification of the present application on page 18 for combination of a compound of Formula I and ezetimibe are unexpected results. The Office has asserted that **additive** effects would be expected by a person of ordinary skill I the art, but the Office has not shown that **synergistic** effects would result from the combination of the teachings of Frick and Castaner. That is, the presently claimed combination produces an effect that is more than additive, it is more than a skilled person would expect to see from the claimed combination. Accordingly, the synergism disclosed in the specification of the present application is evidence that points toward nonobviousness for the presently claimed invention. What the inventors have discovered is a synergistic effect that is not suggested in the teachings of the references cited, either taken singly, or taken in combination.

Withdrawal of the rejections under 35 U.S.C. §103(a) of claims 10-15 and 18 is therefore respectfully requested.

It is believed that no new matter has been introduced by this response.

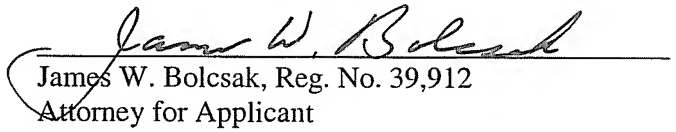
Conclusion

In view of the foregoing discussion, it is believed that all the currently pending claims fully comply with the legal requirements for allowance. Reconsideration and allowance of the application with pending claims are earnestly solicited.

Enclosed herewith is a Petition under 37 C.F.R.§ 1.136(a) to extend the time for response for three months, or until July 26, 2006. It is believed that no additional fees and charges are required at this time in connection with the application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No.18-1982.

If prosecution can be advanced by direct telephone contact with the undersigned, the Office is invited to call the practitioner directly at the number provided below.

Respectfully submitted,



James W. Bolcsak, Reg. No. 39,912
Attorney for Applicant

sanofi-aventis
Patent Department
Route #202-206 / P.O. Box 6800
Bridgewater, NJ 08807-0800
Telephone: (908) 231-5922
Telefax: (908) 231-2626